الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Data Requirements for the Renewal of Marketing Authorizations for human medicinal products

Version 2.0

Date of implementation	10 December 2011

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Saudi Food & Drug Authority

Drug Sector

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Please visit SFDA's website at for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
1.0	Executive Directorate of Product Evaluation and Standards Setting	10 December 2011	Final
1.1	Executive Directorate of Product Evaluation and Standards Setting	24 February 2013	Updated
1.2	Executive Directorate of Product Evaluation and Standards Setting	26 May 2013	Updated
2.0	Executive Directorate of Regulatory Affairs	15 June 2022	Updated

What is New in version no. 1.3 ?

The following table shows the update to the previous version:

Section	Description of change
Module 1	**Delete:** – 1.3 Product Information – 1.7 Certificates and Documents
Module 3	**Delete**: – 3.2. S Drug Substance – 3.2. P.5 Control of Drug Product – 2. P.8 Stability

Table of Content:

1. Introduction:

This document has been developed to assist applicants in the preparation and submission of drug applications for renewal of marketing authorization.

The objectives of this guideline are to classify the requirement of submitting a renewal of marketing authorization and to provide applicants with recommendations on the data required for which may impact the assessment of the drug products.

The following notes should be taken into consideration when submitting any renewal application:

- Renewal applications have to contain a consolidated version of the file, containing at least the documents listed below and presented in accordance with the appropriate headings and numbering of the eCTD format.
- Applicants should be aware that deficient documentation can lead to rejection of the application. In addition, submitting redundant or irrelevant information may delay approval procedures.

2. Scope:

This guideline considers issues associated with the processing of renewals with the aim of giving procedural guidance to marketing authorization holders (MAHs) and applies to all types of human medicinal product registration pathways that are described in the Regulatory Framework for Drugs Approval.

3. Documents to submit:

Module 1:

1.0 Cover letter

- Cover letter must contains the following:
  - All information's about the product which includes the following :
    1. trade name
    2. generic name
    3. sub-product number
    4. request number
    5. strength
    6. dosage form
    7. manufacturer
    8. MAH and agent
  - Cover letter must be applied in an Original MAH paper form.
  - Name of the person authorized to sign on behalf of the company
  - Cover letter must be signed and Stamped from MAH authorized person.

1.2 Application Form

This section should contain the renewal application form according to Request Details in eSDR.

1.8 Pricing

1.8.1 Price list

This section should include the following:

- A price list shall include the price of the drug product in countries listed in the Price Certificate Forms as per pharmaceutical pricing rule.

Abbreviations:

eCTD	electronic common technical document.
SFDA	Saudi food and drug authority.
MAH	Marketing authorization Holder.
eSDR	electronic Saudi drug registry.